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10/599,855	10/11/2006	Navin N. Thakkar	TKKR-002	5789
26392 7590 10/28/2008 LAW FIRM OF NAREN THAPPETA			EXAMINER	
C/O LANDON IP, INC. 1700 DIAGONAL ROAD, SUITE 450 ALEXANDRIA, VA 22314			MERENE, JAN CHRISTOP L	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application No. Applicant(s) 10/599,855 THAKKAR, NAVIN N. Office Action Summary Examiner Art Unit JAN CHRISTOPHER MERENE 3733 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 14 August 2008. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-4.7-9.14.15.18.21.24 and 27-30 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 1-4,7-9,14,15,18,21,24 and 27 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date. Notice of Draftsperson's Patent Drawing Review (PTO-948) Notice of Informal Patent Application 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _ 6) Other:

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DETAILED ACTION

Specification

The substitute specification filed August 14, 2008 has not been entered because
it does not conform to 37 CFR 1.125(b) and (c) because: the applicant has not indicated
the newly added material/ deleted material from the specification (i.e. crossed out lines,
underlining, etc).

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

3. Claims 7, 14 are rejected under 35 U.S.C. 101 because they are drawn to non-statutory subject matter. The, applicant positively recites part of a human, i.e. "gets placed avoiding superior surface..". Thus claims 1-7 include a human within their scope and are non-statutory.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. In re Wakefield, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claims 1-3, 7-9, 14-15, 18, 21, 24, 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "said thigh end." There is insufficient preceding antecedent basis for this limitation in the claim.

Claim 8 recites the limitation "distal locking holes." There is insufficient preceding antecedent basis for this limitation in the claim. The examiner assumes the applicant meant to disclose that the "distal locking holes" are the "first plurality of distal holes." Claim 8 also recites "anterior curvature of femur starts to get sure distal [...] said femur," which is unclear and indefinite. The examiner will treat the last portion of the claim as the distal holes of the targeting device correspond to the distal holes of the nail.

Claim 9 recites the limitation "short length version and long length version."

There is insufficient preceding antecedent basis for this limitation in the claim.

Claim 14 recites the limitation "connecting end of said intramedullary nail." There is insufficient preceding antecedent basis for this limitation in the claim. The examiner will treat the connecting end as the portion that connects to the targeting device.

Claim 15 recites the limitation "short length version," "connecting end of short length version," and "distal locking holes." There is insufficient preceding antecedent basis for this limitation in the claim. The examiner will "treat distal locking holes" as the first plurality of distal holes of the nail. Claim 15 also recites "of femur starts to get sure distal interlocking of said nail [...] said distal holes in said nail," which is unclear and

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indefinite. The examiner will treat the last portion of the claim as the distal holes of the nail correspond to the targeting device.

The examiner has not specifically disclosed every single 112 issue in the claims and respectfully requests the applicant to address such issues, as well as any 101 issues, which positively recites the human body. Claiming part of the human body is non-statutory and the applicant should use terms such as "engagable," "capable of," etc to avoid such issues (see also 101 rejection above).

The claims (especially claims 2-3, 7-9, 14-15, 18) are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

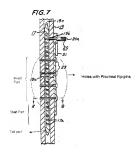
A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States
- Claim 28 is rejected under 35 U.S.C. 102(b) as being anticipated by Bosacco US 3,670,724.

Boasacco discloses an implant assembly for treating proximal femur fractures and same side fractures of shaft of a femur, said shaft portion of said femur containing a medullary canal, said femur containing a neck portion and a head portion, said implant assembly comprising an intramedullary nail (#17) being adapted in use for insertion into

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said medullary canal, said intramedullary nail having a head, an intermediate portion and a knee end portion, wherein said head has a plurality of proximal holes; a buttress plate (#22) having a plurality of central holes; and a plurality of proximal sliding hip pins (#23), each to pass through a corresponding one of said plurality of proximal holes and one of said central holes (see Fig below).



Claim Rejections - 35 USC § 103

- The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zirkle US 2002/0151897 in view of Behrens US 6,932,818.

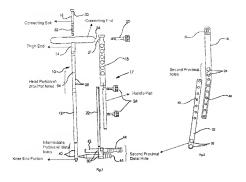
Zirkle discloses an implant assembly comprising, an intramedullary nail with a head, intermediate portion, and a knee end portion, wherein the head portion has a first plurality of distal holes, each with proximal axis oriented at an angle with respect to a

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long axis of the nail defining a first plane, wherein the intermediate portion has a first plurality of distal holes, each with a distal axis oriented at an angle with the long axis of the nail defining a second plane and a targeting device having a connecting end, which can connect to the thigh end with a temporary connecting bolt, a handle part, a block of second plurality of proximal holes corresponding to the first plurality of proximal holes lying on the first plane and a block of second plurality of distal holes corresponding to the first plurality of distal holes lying on the second plane, where the second plurality of proximal holes and the second plurality of distal holes are in different planes (as seen in Figs below and see also paragraph 34, where the first plurality of proximal/distal holes correspond to the second plurality of proximal/distal holes, respectfully, where the first plurality of proximal/distal holes define proximal/distal axis respectfully to form a first and second plane and see Fig 2, where the second plurality of proximal holes and the second plurality of distal holes are in different planes).

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Zirkle does not explicitly disclose the first plurality of proximal holes makes an angle of approximately 120 degrees to the long axis of the nail and the first plurality of distal holes makes an angle of approximately 90 degrees to the long axis of the nail (although the examiner notes that according to the figure below, it appears that the distal holes appear to have an axis with an angle of 90 degrees to the long axis).

However, it would have been obvious to have the proximal/distal holes oriented at 120 degrees/ 90 degrees, respectfully, to the long axis of the nail since the nail is provided adapted to match the curvature of the bone, where it would be obvious to one having ordinary skill in the art at the time the invention was made that the curvature would correspond to a patient according to a patient's need (see paragraph 35).

It would also have been obvious to one having ordinary skill in the art at the time the invention was made to have the proximal/distal holes oriented at 120 degrees/ 90

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degrees, respectfully, to the long axis of the nail, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Furthermore, Behrens discloses a similar assembly with an intramedullary nail (#60) and a targeting device (#90) with first and second proximal holes and first and second distal holes (as in Fig 2), wherein the proximal holes can be oriented at about 120 degrees and the distal holes oriented at 90 degrees (see Col 4 lines 44-50 and see also Col 5 lines 5-15).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the proximal holes to be oriented at 120 degrees and the distal holes to be at 90 degrees because these angles are well known in the art to aid in repairing fractures (see Col 2 lines 30-62, Col 4 lines 45-50 and Col 5 lines 5-15).

 Claim 27, 2-3, 7-8, 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zirkle US 2002/0151897 and Behrens US 6,932,818 as applied to claim 1 above, and further in view of Bosacco US 3,670,724.

Zirkle and Behrens disclose the claimed invention as discussed above, wherein:

in Claim 2, the intramedullary nail has anterior curvature in knee end portion (see paragraph 35, where the nail is can be curved to match the natural curvature of the bone);

in Claim 3, the connecting end of the targeting device has a matching diameter with an in internally threaded part of the intramedulalry nail (as seen above), wherein

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the targeting device is connected by a temporary connecting bolt (as seen in Fig above and see also Fig 3-3a and paragraph 32), wherein the connecting end is short and compact (as seen above, where the connecting end is small and removable from the device) and does not obstruct imaging (see Figs above and also Fig 3, 3a, where the connecting end is connecting only to the top portion of the nail and is removable so as to not obstruct imaging);

in Claim 7, a first distance between a tip of the connecting end and proximal holes is kept at an X value and a second distance between a pair of proximal holes is kept at Y value, wherein X and Y are in millimeters (see Fig above where any number of distances in X can be made between the connecting end and the holes and that the proximal holes are at a distance Y, where the distance between any given point can always be measured in millimeters, where placement of the nail with the pins would be capable of being placed near the calcar portion and a plurality of hip pins would be capable of being placed avoiding a superior surface of a neck portion of the femur, where it can prevent cut through of another one of proximal sliding pins);

in Claim 8, the intramedullary nail is of a short length version (see paragraph 35, where the length of the nail ranges from 12-24," where the nail can be short, depending on the patient need) where there is a distance of Z in millimeters between the connecting end and the distal holes of the targeting device (see Figs above where there is distance between the tip a tip of the connecting end and the distal holes, where the distance can be measured in millimeters), which correspond to the distal holes of the nail (as seen in Fig above).

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in Claim 14, the distance between the tip of the tip of the connecting end of the nail and the first plurality of proximal holes is kept at a distance X1 value, and the distance between the proximal holes is kept at Y1 is kept in millimeters (see Fig above where a distances X1 and Y1 can be formed, where the distance between any two points can be measured in millimeters and where the pins would be capable of being placed near a calcar portion and a plurality of hip pins would be capable of being placed avoiding a superior surface of a neck portion of the femur, where it can prevent cut through of another one of proximal sliding pins);

in Claim 15, the nail can be of a short length version (see paragraph 35), where there is a distance Z1 in millimeters between the connecting end of the nail (where the nail connects with targeting device) to the distal holes of the targeting device (as seen in Figs above and where the distance between two points can be measured in millimeters).

However, Zirkle and Behrens does not specifically a buttress plate having a plurality of central holes; and a plurality of proximal sliding hip pins, each to pass through a corresponding one of said first plurality of proximal holes and one of said central holes.

However, Bosacco discloses an intramedullary nail (#17), a buttress plate (#22) with a plurality of sliding pins (#23) that correspond to holes on the nail (as seen in Figs 6-7).

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It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the assembly of Zirkle and Behrens to include a buttress plate with holes, with a plurality of sliding pins to correspond with a first plurality of proximal holes of the intramedullary nail and holes of the plate because plates are widely known in the art to help treat bone fractures and the plate also helps prevent of the intramedullary nail (see Col 3 lines 19-24), where it would be obvious that the plate would match/correspond with the intramedullary nail.

4. Claim 9, 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zirkle US 2002/0151897 and Behrens US 6,932,818, and Bosacco US 3,670,724 as applied to claim 2 above, and further in view of Brumfield US 5,562,666.

Zirkle, Behrens, and Bosacco disclose the claimed invention as discussed above, where the length of the nail can be varied (see paragraph 35 in Zirkle) but does not specifically disclose an intramedullary nail of a short version or a long length version, that has a reducing cross section area and wall thickness.

However, Brumfield teaches an intramedullary nail of short length version (#110) and long length version (#10) characterized having reducing cross section area and wall thickness of said intramedullary nail gradually from said thigh end portion to said intermediate portion or shaft to said distal knee end portion or tail to match shape of said intramedullary nail implant with shape of intramedullary canal and cortical thickness of femur to avoid high hoop stress in medullary canal while inserting said intramedullary nail (see Fig 12 above for short version and Fig 3 in Brumfield for the long version,

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which shows a cross-section view similar to that of Fig. 12 which shows reduced cross section and wall thickness) and the nails have a central cannulation (see Col 6 lines 50-60).

It would have been obvious to one having ordinary skill in the art to modify the assembly of Zirkle, Behrens, and Bosacco with to provide a short length and long length version of the nail, with reducing cross section area and wall thickness because one would not to ream the entire legnth of the femoral marrow channel if there is no trauma to that area (see Col 5 lines 55-65), where the reduction of the cross sectional area and wall thickness is needed to provide curvature of the nail since the nail does not have a slit, wherein the nail is adapted to align with the marrow canal of the femur (see Col 3 lines 18-24, Col 5 lines 5-15), where the central cannulation allows for the use of a guide wire (see Col 6 lines 50-60). (The examiner also notes that nails of reduced cross sectional areas and wall thickness are used widely in the art to match the anatomy of the bone, see PTO-892).

5. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zirkle US 2002/0151897 and Behrens US 6,932,818, and Bosacco US 3,670,724 as applied to claim 2 above, and further in view of Engelhardt et al US 4,805,607.

Zirkle, Behrens, and Bosacco disclose the claimed invention as discussed above but does not specifically disclose the proximal sliding hip pin comprises a triflanged part with three scalloped flat equal surfaces up to 15mm to 50mm of span, with mores taper toward the leading end.

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However, Engelhardt discloses a pin/nail with a triflanged part, having three equal surfaces (#26 as seen in Figs 5, 7 and 9).

It would have been obvious to one having ordinary skill in the art to modify the proximal sliding hip pin of Zirkle, Behrens, and Bosacco with the tri-flanged part as taught by Engelhardt because it allows bone contact, such as cortical, along three very thin flanges of metal that are equally spaced, where the leading end of each flange is a sharp point that upon nail impaction cuts into the bone and provides a self broaching mechanism (see Col 2 lines 11-16) and that the edges of the flanges digging into the bone reduce the ability of the nail to undesirably rotate inside the bone or the individual bone fragments to rotate relative to the nail or to each other (see Col 4, lines 14-18).

With regards to the flat surfaces span up to 15 to 50mm, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the flat surfaces span up to 15 to 50mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller, 105 USPQ 233.*

Further more, it would have been an obvious matter of design choice to construct the flat surfaces span up to 15 to 50mm, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose, 105 USPQ 237 (CCPA 1955)*.

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6. Claim 21, 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zirkle US 2002/0151897 and Behrens US 6,932,818, Bosacco US 3,670,724, and Engelhardt et al US 4,805,607 as applied to claim 18 above, and further in view of Engelhardt et al US 4,805,607.

Zirkle, Behrens, Bosacco, and Engelhardt disclose the claimed invention as discussed above with a triflanged part at the distal end of the pin but does not specifically disclose the triflanged part has a plurality of holes of at least 2mm in diameter connecting to a central cannulation.

However, Middleton discloses a pin with a central cannulation (#192) and plurality of holes (#134).

It would have been obvious to one having ordinary skill in the art to modify the triflanged part to include the holes (#134) and central cannulation of Middleton because the holes (#134) and central cannulation are adapted for the flow of in-situ hardenable material (see paragraph 34), wherein the material is bone cement (see paragraph 37).

With regards to the diameters of the holes, it would also have been obvious to one having ordinary skill in the art to have holes of at least 2mm due to the small space within the body to sufficiently supply material through the holes.

It would also have been obvious to one having ordinary skill in the to have holes of at least 2mm, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

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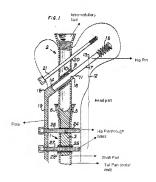
7 Claim 29 are rejected under 35 LLS C 103(a) as he

 Claim 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marino US 4,733,654 in view of Welgum US 5,462,547.

Marino discloses a method of treating a fracture of a femur bone, said fracture being located between the head of said femur and the intramedullary canal of said femur, said method utilizing a buttress plate in combination with an intramedullary nail, said intramedullary nail having a tail part, a shaft part, and a head part, said head part having a plurality of proximal holes, said method comprising:

inserting said intramedullary nail into said intramedullary canal;

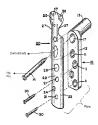
placing said buttress plate on a the lateral cortex, wherein said buttress plate has a central hole; (as seen in Fig below and see Col 1 lines 60-67 – Col 2 lines 1-8), wherein a locking screw (#26) is passed through the .



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However, Marino does not specifically disclose the plate covering a surface of a greater trochanter and inserting the proximal hip pin through said central hole and one of said plurality of proximal holes such that said proximal hip pin extends across the fracture and into the neck and the head of said femur.

However, Weigum discloses a similar buttress plate that is placed on the greater trochanter and lateral cortex of the femur, wherein a hip pin is passed through the central hole (as seen in Figs below and 1, 5-6 and see Col 3 lines 56-61 and Col 4 lines 32-44).



It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the plate of Marino to include the trochanter plate as taught by Weigum because it provides support for the trochanter and also provides apertures #32 which aid in wiring (see Col 4 lines 32-44). It would also have been obvious to modify the plate of Marino so that the hip pin is inserted through the central hole also taught by Weigum because it applies a known technique to a known device/method, ready for improvement to yield predictable results of passing a hip pin

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through a plate, where the pin helps in helping repairing femoral fractures (see Col 3 lines 56-61).

8. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Marino US 4,733,654 and Welgum US 5,462,547 as applied to claim 29 above, and further in view of Vandewealle 5.810.821.

Marino and Welgum disclose the claimed invention as discussed above, wherein the plate has a plurality of distal holes and a locking screw (#30 through hole #11) is inserted through the plate at substantially 90 degrees to the longitudinal axis of the nail (see above, where it would be obvious with the teachings of Marino and Welgum that the locking screw would go through the nail as well), but does not specifically disclose the nail going through the lateral cortex.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to move the relocate the holes of the plate and nail so that the locking screw would go through the lateral cortex at 90 degrees, since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

Furthermore, Vandewealle teaches a similar plate, where a locking screw (#33) is placed through the lateral cortex.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the plate and screw of Marino and Welgum so that a locking screw can go through the lateral cortex as taught by Vanerwealle because it helps another area for positional fixing of the femur (see Col 3 lines 11-13).

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With regard to the statements of intended use and other functional statements in the claims above, they do not impose any structural limitations on the claims distinguishable over the art which is capable of being used as claimed if one so desires to do so.

Response to Arguments

 Applicant's arguments with respect to claims 1-3, 7-9, 14-15, 21, 24, 27-29 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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The prior art made of record and relied upon is considered pertinent to the applicant's disclosure. See PTO-892 for art cited of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAN CHRISTOPHER MERENE whose telephone number is (571)270-5032. The examiner can normally be reached on 8 am - 6pm MonThurs, alt Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jan Christopher Merene/ Examiner, Art Unit 3733

/Eduardo C. Robert/ Supervisory Patent Examiner, Art Unit 3733